Consent Form

Title of Research Study: ***Mindful Breathing and Neuromodulation for Depression in Young People***

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Kathryn Cullen, MD Department of Psychiatry Phone Number: 612-273-9762 Email Address: rega0026@umn.edu	Study Staff: Michelle Thai Phone Number: (612) 626-6870 Email Address: thaix049@umn.edu

If your provider is also the person responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the University of Minnesota's College of Liberal Arts Brain Imaging Grants awarded to Dr. Bonnie Klimes-Dougan and Michelle Thai, by the University of Minnesota's College of Liberal Arts Office of Faculty and Academic Affairs Social Sciences seed grant awarded to Dr. Bonnie Klimes-Dougan, a Grant-in-Aid of Research, Artistry and Scholarship (GIA) awarded to Dr. Bonnie Klimes-Dougan, Center for Magnetic Resonance Research Commitment Pool funding awarded to Dr. Kathryn Cullen, Clinical Translational Research Services (CTRS) Pilot Funding Program awarded to Dr. Kathryn Cullen by National Center for Advancing Translational Sciences of the National Institutes of Health Award Number UL1TR002494, American Psychological Foundation/Council of Graduate Departments of Psychology (APF/COGDOP) 2020 Clarence J. Rosecrans Scholarship awarded to Michelle Thai, by Dr. Kelvin Lim's professional funds, and a Lou Ann Nylen Research Award awarded to Michelle Thai.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual,

may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have current symptoms of depression.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
In this study, we hope to look at the effects of practicing mindful breathing training (MBT), a type of meditation, combined with transcranial direct current stimulation (tDCS) for depression. tDCS is a type of noninvasive electrical brain stimulation. The results from this study may help develop new ways to treat depression in the future.

How long will the research last?
We expect that you will be in this research study for up to 9 weeks.

What will I need to do to participate?
You will be asked to attend all study visits and follow the instructions given to you by the study staff. You will complete a diagnostic interview, complete questionnaires, do computer tasks, have EEGs (a way to measure brain activity) and ECGs (a way to measure heart activity), have an MRI (a way to take pictures of your brain), undergo brain stimulation, and practice MBT at home.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?
Transcranial Direct Current Stimulation (tDCS): tDCS has shown to be a safe brain stimulation technique. The most common side effects are mild, including itching or discomfort under the electrode at the beginning of administration, headache, fatigue, dizziness, and nausea, which typically resolve at the end of stimulation.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include an improvement in your symptoms of depression.

What happens if I do not want to be in this research?
Treatment alternatives are those offered in usual care. The study doctor can tell you more about these options.

Detailed Information About This Research Study
The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 75 people here will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?
If you decide to participate in this study, you may expect the following:

Week 1:

- You will have your baseline assessment, which will last about 2 ½ hours. This will include a diagnostic interview, questionnaires, and a computer task.
- You will have an EEG and ECG, about 2 hours total. For the EEG, lab staff will place a cap on your head. You will be asked to sit quietly with your eyes opened and closed. You will be asked to describe a negative thought and a neutral you have had and fixate on these for three minutes each. You will also be asked to complete a couple of tasks where you respond to certain stimuli, like arrows. For the ECG, lab staff will place sticky pads on your wrists to measure your heart rate variability (how your heart rate changes as you breathe in and out).
- You can choose to have an optional MRI that will take 2 hours total. You will be instructed to remove all metallic objects and you will lay down inside the MRI machine. You may hear some loud noises during the scan. You will be asked to lay quietly for 12 minutes. You will be asked to complete a matching task with shapes and faces for 6 minutes. You will be asked to think about different statements for 20 minutes. You will also be asked to lay still for 15 minutes while they take a picture of your brain.
- You will also be asked to provide eight saliva samples when you are at home across two days and bring them back to the next appointment. You will also be asked to fill out a "daily diary" that accompanies the samples and provides information related to the day.

Week 2:

- You will practice MBT at home five times. You will be instructed on how to do this during your last week 1 visit. During this training, you will complete your first at-home training. You will have a guided computerized task to help you. You will be asked to focus on the sensations of your breath and receive feedback on how you are doing.

  Your first five sessions of MBT will take a little bit longer each time:
  - First MBT session will take 10 minutes

- Second MBT session will take 12 ½ minutes
- Third MBT session will take 15 minutes
- Fourth MBT session will take 17 ½ minutes
- Fifth MBT session will take 20 minutes

Week 3:

- You will receive either tDCS or sham five times, along with MBT. Each session will take about an hour total.
- You will have your interim assessment, which will last about 15 minutes.

Week 4:

- You will receive either tDCS or sham five times, along with MBT. Each session will take about an hour total.

Week 5:

- You will have your post-tDCS assessment, which will last about 1 hour.
- You will have an EEG and ECG, about 2 hours total. During this EEG, in addition to the tasks you do at the first EEG, you will also be asked to practice mindful breathing for 10 minutes.
- If you underwent the MRI during the baseline assessments, you will have an MRI that will take 2 hours. In addition to the tasks you do at the first MRI, you will be asked to practice mindful breathing for 12 minutes.
- You will provide eight saliva samples across two days and bring these samples back during your next appointment. You will complete the "daily diary."

Weeks 6-8:

- You will practice MBT at home five times a week, for 20 minutes each.

Week 9:

- You will have your final assessment, which will last about 1 hour.
- You will have an EEG and ECG, about 2 hours total.

On rare occasions, the MRI or EEG data that we collect does not have the high quality that we need for data analyses or we are unable to collect the data that we need. If this were to happen, we will invite you to return to repeat all or a portion of the MRI or EEG visit. This would be scheduled as soon as possible after your visit. If you agree to repeat the EEG or MRI visit, you will be compensated again. If there is a month or longer delay between the last baseline assessment visit (e.g., initial assessment, EEG, or MRI), you may be asked to repeat some or all of the baseline research visits and will be paid accordingly.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

If you decide to leave the research study, contact the investigator so that the investigator can ask you some questions about the study to help you leave the study safely or to collect more information for the

study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

Data that has already been collected about you will not be destroyed, but new information will not be collected.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Clinical Assessments: You may experience mild stress, discomfort, or fatigue during the clinical assessment or while completing self-report or behavioral assessments. The assessments may involve questions about feelings, past experiences, and family history. You only need to share what you feel comfortable with and you will not be forced to discuss anything that makes you too uncomfortable.

Behavioral Tasks: These tasks may be tiring. Some tasks may ask you to think about negative thoughts or involve negative stimuli that may cause mild stress, discomfort, or fatigue.

MRI: MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are:

Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk, we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.

Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.

Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the investigator.

Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. Pre-scan procedures will also include a drug test. You will be informed of these results. You will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of the magnetic field.

EEG/ECG: Mild skin irritation may occur at the electrode placement site (e.g., redness).

Will I receive any imaging results after an MRI?

The images or pictures created during this study are for research purposes only and are not intended to provide health care to you. However, if the results from the magnetic resonance imaging show something unusual in the pictures, a Radiologist trained in reading the pictures will look at them. The pictures will not contain any personal information except your age and pertinent medical history collected as part of the research. There will be no charge to you for having the Radiologist look at your pictures. The investigator Dr. Kathryn Cullen will contact you if the recommendation of the Radiologist is to further investigate the unusual results of the pictures with your own physician. However, further medical follow up is not a part of this study and the study does not have funds set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The risks of high magnetic fields in the MRI scanner and the effects of direct current stimulation of the brain are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, you should use a reliable form of birth control. If you have any reason to believe that you might be pregnant, you should not participate in this study. You will have a pregnancy test before you undergo each MRI scan. If the test shows that you are pregnant, you cannot complete any MRI or tDCS sessions. You will be informed if your pregnancy test is positive.

Will I know about any new information about the effects of MRIs on human health?

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal

(e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you experience severe adverse events, active suicidal ideation, or any unanticipated problems where the study doctor feels it would be unsafe for you to continue on the study.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you as follows for your time and effort.

- $20 for your consent visit
- $15 for your baseline EEG/ECG visit
- $15 for your post-tDCS EEG/ECG visit
- $15 for your final EEG/ECG session
- $40 for your pre-treatment MRI scan

- $40 for your post-treatment MRI scan
- $5 for providing your baseline saliva samples and daily diary
- $5 for providing your post-tDCS saliva samples and daily diary
- $10 for your post-tDCS assessment visit
- $15 for your final assessment visit
- $5 for Week 1 assessment

This totals $185 if all study visits are completed.

If you complete all study visits, you will be entered into a raffle to win $50.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

University of Minnesota Undergraduate students may also choose to receive 10 Research Experience Points (REP) points awarded through the Department of Psychology instead of money for their consent visit.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

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Investigator Name: Kathryn Cullen, MD Department of Psychiatry Phone Number: 612-273-9762 Email Address: rega0026@umn.edu	Study Staff: Michelle Thai Phone Number: (612) 626-6870 Email Address: thaix049@umn.edu

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Key Information About This Research Study

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What is research?

Doctors and investigators are committed to your child's care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. Your child, as an

individual, may or may not be helped by volunteering for a research study.
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Why is my child being asked to take part in this research study?

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What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you and your child.
- You can choose not to allow your child to take part.
- You can agree to allow your child to take part and later change your mind.
- Your decision will not be held against you or your child.
- You can ask all the questions you want before you decide.

Why is this research being done?

In this study, we hope to look at the effects of practicing mindful breathing training (MBT), a type of meditation, combined with transcranial direct current stimulation (tDCS) for depression. tDCS is a type of noninvasive electrical brain stimulation. The results from this study may help develop new ways to treat depression in the future.

How long will the research last?

We expect that your child will be in this research study for up to 9 weeks.

What will my child need to do to participate?

Your child will be asked to attend all study visits and follow the instructions given to him or her by the study staff. He or she will complete a diagnostic interview, complete questionnaires, do computer tasks, have EEGs (a way to measure brain activity) and ECGs (a way to measure heart activity), have an MRI (a way to take pictures of the brain), undergo brain stimulation, and practice MBT at home.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want my child to be in this research?"***

Is there any way that being in this study could be bad for my child?

Transcranial Direct Current Stimulation (tDCS): tDCS has shown to be a safe brain stimulation technique. The most common side effects are mild, including itching or discomfort under the electrode at the beginning of administration, headache, fatigue, dizziness, and nausea, which typically resolve at the end of stimulation.

More detailed information about the risks of this study can be found under ***"What are the risks of this***

study? Is there any way being in this study could be bad for my child? (Detailed Risks)"

Will being in this study help my child in any way?

We cannot promise any benefits to your child or others from taking part in this research. However, possible benefits include an improvement in your child's symptoms of depression.

What happens if I do not want my child to be in this research?

Treatment alternatives are those offered in usual care. The study doctor can tell you more about these options.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 75 people here will be in this research study.

What happens if I say "*Yes, I want my child to be in this research*"?

If you decide to allow your child to participate in this study, you and your child may expect the following:

Week 1:

- Your child will have your baseline assessment, which will last about 2 ½ hours. This will include a diagnostic interview, questionnaires, and a computer task.
- Your child will have an EEG and ECG, about 2 hours total. For the EEG, lab staff will place a cap on your child's head. Your child will be asked to sit quietly with your eyes opened and closed. Your child will be asked to describe a negative thought and a neutral thought your child has had and fixate on these for three minutes each. Your child will also be asked to complete a couple of tasks where your child responds to certain stimuli, like arrows. For the ECG, lab staff will place sticky pads on your child's wrist to measure your child's heart rate variability (how your heart rate changes as you breathe in and out).
- Your child can choose to have an optional MRI that will take 2 hours total. Your child will be instructed to remove all metallic objects and your child will lay down inside the MRI machine. Your child may hear some loud noises during the scan. Your child will be asked to lay quietly for 12 minutes. Your child will be asked to complete a matching task with shapes and faces for 6 minutes. Your child will be asked to think about different statements for 20 minutes. Your child will also be asked to lay still for 15 minutes while they take a picture of their brain.
- Your child will also be asked to provide eight saliva samples when your child is at home across two days and bring them back to the next appointment. Your child will also be asked to fill out a "daily diary" that accompanies the samples and provides information related to the day.

Week 2:

- Your child will practice MBT at home five times. Your child will be instructed on how to do this during your child's last week 1 visit. During this training, your child will complete his or her first at-home training. Your child will have a guided computerized task to help him or her. Your child will be asked to focus on the sensations of his or her breath and will receive feedback on how he

or she is doing.

Your child's first five sessions of MBT will take a little bit longer each time:

- First MBT session will take 10 minutes
- Second MBT session will take 12 ½ minutes
- Third MBT session will take 15 minutes
- Fourth MBT session will take 17 ½ minutes
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Week 3:

- Your child will receive either tDCS or sham five times, along with MBT. Each session will take about an hour total.
- Your child will have an interim assessment, which will last about 15 minutes.

Week 4:

- Your child will receive either tDCS or sham five times, along with MBT. Each session will take about an hour total.

Week 5:

- Your child will have your post-tDCS assessment, which will last about 1 hour.
- Your child will have an EEG and ECG, about 2 hours total. During this EEG, in addition to the tasks your child does at the first EEG, your child will also be asked to practice mindful breathing for 10 minutes.
- If your child underwent the MRI during the baseline assessments, your child will have an MRI that will take 2 hours. In addition to the tasks your child does at the first MRI, your child will be asked to practice mindful breathing for 12 minutes.
- Your child will provide eight saliva samples across two days and bring these samples back during your child's next appointment. Your child will complete the "daily diary."

Weeks 6-8:

- Your child will practice MBT at home five times a week, for 20 minutes each

Week 9:

- Your child will have a final assessment, which will last about 1 hour.
- Your child will have an EEG and ECG, about two hours total.

On rare occasions, the MRI or EEG data that we collect does not have the high quality that we need for data analyses or we are unable to collect the data that we need. If this were to happen, we will invite your child to return to repeat all or a portion of the MRI or EEG visit. This would be scheduled as soon as possible after your child's visit. If your child agrees to repeat the EEG or MRI visit, your child will be compensated again. If there is a month or longer delay between the last baseline assessment visit (e.g., initial assessment, EEG, or MRI), your child may be asked to repeat some or all of the baseline research visits and they will be paid accordingly.

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If you decide you want your child to leave the research study, contact the investigator so that the investigator can ask your child some questions about the study to help him or her leave the study safely or to collect more information for the study.

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Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk, we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling access to the scanner.

Claustrophobia: The scanner is a long narrow tube that may cause some people to feel claustrophobic.

Hearing Damage: The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if you do not wear hearing protection. Hearing protection is required and is provided by the investigator.

Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.

Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you have any implanted device notify the investigator.

Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. Pre-scan procedures will also include a drug test. Your child will be informed of these results. To protect your child's privacy, we will not share these results with you. Your child will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if he or she notices anything unusual, becomes claustrophobic, thinks that your hearing protection is not adequate, or if he or she experiences nerve stimulation that is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, your child should notify the researcher right away and his or her participation will stop and he or she will be taken out of the magnetic field.

EEG/ECG: Mild skin irritation may occur at the electrode placement site (e.g., redness).

Will my child or I receive any imaging results after an MRI?

The images or pictures created during this study are for research purposes only and are not intended to provide health care to your child. However, if the results from the magnetic resonance imaging show something unusual in the pictures, a Radiologist trained in reading the pictures will look at them. The pictures will not contain any personal information except your child's age and pertinent medical history collected as part of the research. There will be no charge to you for having the Radiologist look at your child's pictures. The investigator Dr. Kathryn Cullen will contact you if the recommendation of the Radiologist is to further investigate the unusual results of the pictures with your child's own physician. However, further medical follow up is not a part of this study and the study does not have funds set aside for this purpose. Therefore, if the results do show something unusual, any medical follow up cost will be your responsibility and/or the responsibility of your health insurance carrier.

What do I need to know about reproductive health and/or sexual activity if my child is in this study?

The risks of exposure to high magnetic fields in the MRI scanner and the effects of direct current

stimulation of the brain are unknown for fetuses. Therefore, if your child is a female who is capable of becoming pregnant, your child should use a reliable form of birth control. If you have any reason to believe that she might be pregnant, she should not participate in this study. Your child will have a pregnancy test before your child undergoes each MRI scan. If the test shows that your child is pregnant, your child cannot complete any MRI or tDCS sessions. Your child will be informed if your child's pregnancy test is positive. To protect your child's privacy, we will not share these results with you unless we feel the pregnancy would cause serious problems for your child.

Will I know about any new information about the effects of MRIs on human health?

You will be told of any important new information that is learned during the course of this research study, which might affect your child's condition or your willingness to continue to allow your child's participation in this study.

Will it cost me anything for my child to participate in this research study?

Taking part in this research study will not lead to any costs to you.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your child's information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

Your child's information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your child's identifiers are removed.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your child's medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your child's name and other identifying information confidential.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for

health care. The investigator(s) will not contact you or share your child's individual test results.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you or your child. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my child's experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your child's rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your child's experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my child's experience?" of this form for HRPP contact information.

Can my child be removed from the research?

The person in charge of the research study or the sponsor can remove your child from the research study without your approval. Possible reasons for removal include if your child experiences severe adverse events, active suicidal ideation, or any unanticipated problems where the study doctor feels it would be unsafe for him or her to continue on the study.

What happens if my child is injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that your child has suffered a research related injury let the study physicians know right away.

Will my child be compensated for his or her participation?

If you agree to allow your child to take part in this research study, we will pay your child as follows for his or her time and effort.

- $20 for your consent visit
- $15 for your baseline EEG/ECG visit
- $15 for your post-tDCS EEG/ECG visit
- $15 for your final EEG/ECG session
- $40 for your pre-treatment MRI scan
- $40 for your post-treatment MRI scan
- $5 for providing your baseline saliva samples and daily diary
- $5 for providing your post-tDCS saliva samples and daily diary
- $10 for your post-tDCS assessment visit
- $15 for your final assessment visit
- $5 for Week 1 assessment

This totals $185 if all study visits are completed.

If you complete all study visits, you will be entered into a raffle to win $50.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give your child a debit card and each time he or she receives a payment for participation in this study, the money will be added to the card after each completed visit.

Your child may use this card at any store that accepts MasterCard or he or she can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give your child the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. Your child will also receive letters with additional information on how he or she can use this card and who to call if he or she has any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your child's name. They will use this information only as part of the payment system. Your child's information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your child's health status or the study in which he or she is participating.

Use of Identifiable Health Information

We are committed to respect your child's privacy and to keep his or her personal information confidential. When choosing to take part in this study, you are giving us the permission to use your child's personal health information that includes health information in his or her medical records and information that can identify him or her. For example, personal health information may include your

child's name, address, phone number or social security number. Those persons who get your child's health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your child's information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Permission for Future Re-Contact

I will allow the members of the study team to contact me in the future to request information about my child's progress or to see whether my child and I would be interested in participating in other research studies by the study team. If my child is not eligible at the time of the baseline assessment but my child is expected to meet eligibility criteria at a later point in time (e.g., depression scores are too low), I may be re-contacted within 3 months of my child's baseline assessment for my child to be re-assessed. If I agree to be re-contacted but my child is not eligible or my child chooses not to be in the study right now, I do not have to sign at the end of this consent form. Please initial next to the appropriate choice below: Please initial next to the appropriate choice below:

_____ I do not agree to be re-contacted.

_____ I agree to be re-contacted.

Signature Block:

Your signature documents your permission for the named child to take part in this research. You acknowledge that you have had an opportunity to ask all of your questions and you have received answers to those questions. You will be provided a copy of this signed document.

_____
Printed Name of Child

_____ _____
Signature of Parent or Guardian Date

_____
Printed Name of Parent or Guardian

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Permission for Future Re-Contact

I will allow the members of the study team to contact me in the future to request information about my progress or to see whether I am interested in participating in other research studies by the study team. Please initial next to the appropriate choice below:

_____ I do not agree to be re-contacted.

_____ I agree to be re-contacted.

Signature Block:

Your signature documents your permission to take part in this research. You acknowledge that you have had an opportunity to ask all of your questions and you have received answers to those questions. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Assent Form

University of Minnesota

Assent to Participate in Research

Title of Research Study: ***Mindful Breathing and Neuromodulation for Depression in Young People***

Researcher: ***Kathryn Cullen, MD***

What is research?

Doctors and researchers are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of kids in the future. Researchers learn things by asking a question, making a plan, and testing it. In some kinds of research they are trying to find new ways to help kids feel better. They do not know if the new medicine or treatment will work.
- The goal of treatment is to help you get better by using medication, therapy, surgery or other things that usually makes kids feel better. Sometimes treatments help make you feel better or get rid of the condition completely. Doctors can make changes to your treatment plan as needed.

Why am I being asked to take part in this research study?

A research study is usually done to find a better way to treat people or to understand how things work. You are being asked to take part in this research study because you have current symptoms of depression.

What should I know about being in a research study?

You do not have to be in this study if you do not want to be. It is up to you if you want to participate and if you want to, talk to your parents about any questions or concerns you have about the study. You can choose to take part now and change your mind later if you want. If you decide you do not want to be in this study, no one will be mad at you. You can ask all the questions you want before you decide.

Why is this research being done?

In this study, I want to look at the effects of practicing mindful breathing training (MBT), a type of meditation, combined with transcranial direct current stimulation (tDCS) for depression. tDCS is a type of noninvasive electrical brain stimulation. The results from this study may help develop new ways to treat depression in the future.

How long will the research last?

I expect that you will be in this research study for up to 9 weeks.

What happens if I say "Yes, I want to be in this research"?

If you decide to participate in this study, you may be asked to complete some questionnaires, answer questions in an interview, do computer tasks, and an EEG. You can also choose to complete an optional MRI scan. You may be asked some hard questions about things like distressing events in your life or suicidal thinking. You do not have to answer any question that makes you uncomfortable. The computer tasks look at things like your attention and ability to shift focus. An MRI scan is to get a "picture" of your brain. During an EEG, you will wear a cap, like a swimming cap, with electrodes that will record brain activity. We will also do an ECG to measure your heart activity by placing a sticky pad on your wrists. During the MRI and EEG scans, sometimes you will rest and sometimes we will ask you to think about certain thoughts, focus on different things, and match pictures and shapes. You will take a drug test before each MRI test and we will tell you the results. We will also ask you to spit into some small containers at home.

After you complete these visits, we will ask you to practice mindful breathing training on a computer application. For one week, you will practice at home 5 times. You will complete your first practice when we show you how to use the application after your EEG or MRI appointment. Then for 10 visits, we will have you practice with tDCS, a form of brain stimulation, or sham.

After you complete the tDCS visits, we will ask to repeat some of the questionnaires, computer tasks, and the EEG as well as spit into the containers and home. If you completed the MRI scan during your first week, we will have you repeat the MRI. Then we will have you practice the mindful breathing training for 3 weeks at home. Afterwards, we will have you repeat some of the questionnaires, computer tasks, and EEG.

On rare occasions, the MRI or EEG data that we collect does not have the high quality that we need for data analyses or we are unable to collect the data that we need. If this were to happen, we will invite you to return to repeat all or a portion of the MRI or EEG visit. This would be scheduled as soon as possible after your visit. If you agree to repeat the EEG or MRI visit, you will be compensated again. If there is a month or longer delay between the last baseline assessment visit (e.g., initial assessment, EEG, or MRI), you may be asked to repeat some or all of the baseline research visits and will be paid accordingly.

Important information for girls

Because of the possible risk, you cannot participate in this study if you are pregnant or breastfeeding. You will have a pregnancy test before you undergo each MRI scan. If the test shows that you are pregnant, you cannot complete any MRI or tDCS sessions.

Your parent/guardian will not be told the results of the pregnancy test without your permission. But,

if your doctor believes that being pregnant may cause serious problems for your health, they may be forced to tell your parent/guardian the pregnancy test results.

If you are sexually active, you must agree to use an approved method of birth control during the study. Your study doctor or nurse can discuss acceptable methods of birth control with you.

What happens to the information collected for the research?

The researchers will share your information, including research study records, to only people who have a need to review this information. For example, sometimes researchers need to share information with the University or other people that work in research to make sure the researchers are following the rules.

What else do I need to know?

If you agree to take part in this research study, the researcher will pay you as follows for your time and effort.

- $20 for your consent visit
- $15 for your baseline EEG/ECG visit
- $15 for your post-tDCS EEG/ECG visit
- $15 for your final EEG/ECG session
- $40 for your pre-treatment MRI scan
- $40 for your post-treatment MRI scan
- $5 for providing your baseline saliva samples and daily diary
- $5 for providing your post-tDCS saliva samples and daily diary
- $10 for your post-tDCS assessment visit
- $15 for your final assessment visit
- $5 for Week 1 assessment

This totals $185 if all study visits are completed.

If you complete all study visits, you will be entered into a raffle to win $50.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

Who can I talk to?

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Kathryn Cullen, MD Department of Psychiatry Phone Number: 612-273-9762	Study Staff: Michelle Thai Phone Number: (612) 626-6870 Email Address: thaix049@umn.edu

Assent Form

Email Address: rega0026@umn.edu	

This research has been reviewed and approved by an Institutional Review Board (IRB), a group of people that look at the research before it starts. This group is part of the Human Research Protection Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team or your parents.
- You have questions about your rights as a research participant.
- You want to get information or provide feedback about this research.

Signature Block for Child Assent

You have the right to choose not to sign this form for any reason. If you do not sign, you cannot participate in this study.

Signing here means that you have read this form or had someone read it to you. If you don't want to be in this study, don't sign. Signing means that you are willing to be in this study. You will get a copy of this form to keep.

_____ _____

Signature of child Date

_____

Printed name of child

_____ _____

Printed name of person obtaining assent Date

_____

Signature of person obtaining assent

UNIVERSITY OF MINNESOTA

PERMISSION TO USE PERSONAL HEALTH INFORMATION FOR RESEARCH
HIPAA[1] AUTHORIZATION FORM

IRB Study Number: STUDY00004214
Study Title: Mindful Breathing and Neuromodulation for Depression in Young People
Principal Investigator Name: Kathryn Cullen, MD
Principal Investigator Mailing Address: F268 West Building | 2450 Riverside Avenue | Minneapolis, MN 55454
Version date: 16 September 2019

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, your health care provider cannot release your health information for research purposes unless you give your permission. The purpose of this form is to give your permission to your health care provider to release your personal health information to the research team. Your information may then be used by the research team for the research described in the Consent Form, and may also be shared by the research team with others, including those who support the research, have oversight over the research, or sponsor the research, as explained below. This form also describes the type of personal health information that would be released by your health care provider. If you decide to give your permission and to participate in the study, you must sign this form and the Consent Form. You should be aware that once your personal health information is released by your health care provider it may not be protected by privacy laws, and might be shared with others beyond those described in this form or the Consent Form. If you have any questions about this form or the use of your information, ask a member of the research team.

B. What information will be released?

The research team has marked the boxes below for information needed to participate in this study. If you sign this form, your health care provider will release your personal health information as marked below:

- ☐ All Hospital Records
- ☒ All Clinic Records
- ☐ Emergency Dept. Records
- ☐ Dental Records
- ☐ Immunization Records
- ☒ History & Physical Exams
- ☐ Imaging Reports
- ☒ Progress Notes
- ☐ Psychological Tests
- ☐ EEG/EKG/ECHO Reports
- ☐ Lab & Pathology Reports
- ☐ Financial Records

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

☐ Images ☐ Other (describe): Click or tap here to enter text.

C. What about more sensitive health information?

Certain personal health information is so sensitive that it requires your specific permission. If the research study you are participating in requires any of this information, the boxes below will be marked and you will be asked to initial to permit the release of this information to the research team.

☐ I agree to the release of drug and alcohol abuse, diagnosis and treatment records. ____(initial)
☐ I agree to the release of HIV/AIDS testing records.____ (initial)
☐ I agree to the release of genetic testing records._____ (initial)
☒ I agree to the release of mental health diagnosis or treatment records._____ (initial)
☐ I agree to the release of sickle cell anemia records._____ (initial)

D. Who will receive and use my health information?

Your personal health information may be shared with:

1. The research team conducting the research described in the Consent Form, including any affiliated research institutions involved in conducting the research described in the Consent Form;
2. Others at M Health and the University of Minnesota who provide support for the research or who have authority to oversee research (such as systems administrators and other technical and/or administrative support personnel, compliance and audit professionals, individuals involved in processing any compensation you may receive for your participation, and others);
3. The research sponsor(s), any affiliates or partners of the sponsor(s) involved in the research, organizations funding the research, and any affiliates or partners of the funding organization(s) involved in the research;
4. Other organizations who provide accreditation and oversight for the research team; and Others who are authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration or the Office of Human Research Protections, or government agencies in other countries).

E. Am I required to sign this document?

No, you are not required to sign this document. However, if you do not sign the document, you will not be able to participate in this research study and will not receive any treatment that may be provided through the study. Any other treatment, payment, enrollment or eligibility for benefits will not be affected by your decision about signing this document.

F. Will I be able to view my records?

To make sure that the research study is not impacted by any actions you take, it is possible that the research team may not allow you to see the information collected for this study, including

information placed in your medical records, until after the study is complete. Once the study is over, you may view the records.

G. Optional research activity

The study that you are participating might have optional research activities associated with it, such as the creation of a database for possible future research, as described in the Consent Form and as marked below by the research team. If you agree to permit your information to be used for those optional research activities, you must initial below.

- ☐ There are no optional research activities**.** _____ (initial)
- ☒ The research I am participating in has an additional optional research activity to create a database for possible future research, as explained in the Consent Form. I understand I can agree to have my information shared for this purpose or not. _____(initial)
- ☐ The research I am participating in has an additional optional research activity to create a tissue or biospecimen repository for possible future research, as explained in the Consent Form. I understand I can agree to have my information shared for this purpose or not. _____ (initial)

H. Does my permission expire?

This permission expires when the research ends and all required study monitoring is over, including any optional research activities I agree to above.

I. Can I cancel my permission?

You can cancel your permission at any time. To cancel your permission, you can write to the researcher at the address at the top of this form. If you cancel your permission, you will no longer be in the research study. You may want to ask someone on the research team if canceling will affect any research related medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for the research study. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

If you agree to the use and release of your personal health information as described in this document, please print your name and sign below. You will be given a signed copy of this form**.**

_____
Research Participant's Name (print) (*required even if signed by parent/legal representative*)

_____ _____
Research Participant's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the Personal Health Information of the Research Participant named above, please print your name and sign below.

_____
Parent or Legally Authorized Representative's Name (print)

_____
Relationship to the Research Participant

_____ _____
Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the Research Participant because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____
Witness' Name (print)

_____ _____
Witness' Signature Date

Instructions for Researchers: <u>Do not make any changes</u> to this form other than the following items:

The IRB **will not** be confirming the accuracy of the information you complete on this form. The researchers are responsible for accurately completing the HIPAA Research Authorization as follows:

1. Section B: Mark all sources of PHI that will be released to the research team from M Health or other providers.

2. Section C:
   a. Check the box ***only*** for each specific type of information that will be collected for this study
   b. Records for drug and alcohol abuse, diagnosis and treatment are records related to admissions to treatment centers; records for mental health diagnosis or treatment are records related to admissions to mental health units
   c. Obtain the participant's initials ***only*** *for the specific types of information checked*

3. Section G:
   a. Check the boxes indicating if there are optional research activities or not
   b. Obtain the participant's initial *only if the study involves optional research activity*

4. Section J: Obtain the participant's name, signature, and date; *complete subsequent signature lines* ***if applicable***

5. Provide the subject with a signed copy of the form

Note: This form allows you to check the boxes electronically. You can make a 'master version' of this form for this study with all pertinent boxes checked.